

Application No. 10/647,068
Docket No. 0101-P02977US1

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Examiner: Philogene, P.

REMARKS

Claims 1-8 and 12-66 are pending in the application with claims 9-11 canceled above, of which no claims stand allowed. Claims 1-4, 7, and 12 are amended as indicated above, and dependent claims 14-66 are newly added above, the inclusion of which Applicant believes will not unduly burden the examiner, since the newly added dependent claims all depend from independent claims which Applicant believes to be allowable for the reasons set forth below. Since a first action on the merits has been received in the instant application before November 1, 2007, Applicant understands that new rule 1.75(b) limiting the number independent claims to 5 and total claims to 25 does not apply, based on United States Patent and Trademark Office guidance provided at <http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html>.

MISSING COPIES OF PREVIOUSLY SUBMITTED IDS's

Applicants respectfully request that the Examiner provide signed and dated copies of the following previously submitted IDSs which are identified in the table below. (Applicant respectfully reminds the Examiner that IDSs dated on or before April 30, 2007 were filed during the period when prosecution was suspended in order to get the references before the Examiner prior to the first action. Thus, Applicant is still entitled to a non-final action that applies any art of these timely filed IDSs.)

Date Submitted	EFS ID	No. of Pages	First entry on IDS (or sheet)
Nov. 21, 2003 (sheet 12)	n/a	13	Davydov
Sep. 13, 2004	n/a	5	774529 Nieschang
Feb. 28, 2005 (sheet 7)	n/a	10	Rebuttal Expert Report
Apr. 13, 2007	1679851	10	5217009 Kronberg
Apr. 15, 2007	1683947	8	1000001 Holtz
Apr. 15, 2007	1683947	8	5101808 Kobayashi
Apr. 15, 2007	1683947	8	5919476 Fischer
Apr. 15, 2007	1683947	6	6323146 Pugh
Apr. 16, 2007	1684175	5	Svedman
Apr. 16, 2007	1684118	6	Trial Transcript June 1, 2006
Apr. 18, 2007	1694341	7	4822278 Oliva, et al.

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Apr. 18, 2007	1692324	5	Parikh
Apr. 19, 2007	1692213 ; 1692238	7	Plaintiff's first amended complaint
Apr. 19, 2007	1692213 ; 1692238	7	Joint motion for entry of order
Apr. 23, 2007	1705347	8	4969880 Zamierowski
Apr. 23, 2007	1705347	6	20020143286 Tumey
Apr. 23, 2007	1703204	7	Expert Report Michael Baniak
Apr. 23, 2007	1701954	6	Opposition to EP 0,620,720
Apr. 23, 2007	1702262	5	Davydov
Apr. 23, 2007	1694213; 1700681	5	Deposition of Penny Campbell
Apr. 24, 2007	1705564	5	US 10/227,161 Official Action
Apr. 24, 2007	1705158; 1705224	4	WO 93/09727
Apr. 24, 2007	1705158; 1705224	8	DE 19722075
Apr. 27, 2007	1722226	5	Slides, drawings and photographs
Apr. 30, 2007	1726856	8	3M TM Tegaderm
May 1, 2007	1727187	8	Fleischmann
May 1, 2007	1731670	8	Mulder
May 2, 2007	1736137; 1732126	7	Argenta
May 3, 2007	1742225	5	6840960 Bubb
May 4, 2007	1744945	4	20010029956 Argenta
May 4, 2007	1744775	5	Slides and photographs of patient treatment
May 7, 2007	1746431	7	Argenta
May 7, 2007	1748527	10	6936037 Bubb
May 8, 2007	1753729	8	McGuiness
Jun. 21, 2007	1895115	4	4256109 Nichols
Jun. 25, 2007	1905832	4	Egnell
Jul. 5, 2007	1937076	4	McFarlane

PROVISIONAL DOUBLE PATENTING REJECTIONS
OVER 10/647,068 AND 10/161,076

Claims 1-13 stand “provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/227,161.” Claims 1-13 also stand “provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45, 96-103, and 113-121 of copending Application No. 10/161,076 in view of Dunn et al. (5,717,030)...” Solely as an expediency to advance prosecution of the application, Applicant is submitting terminal disclaimers herewith to overcome the provisional double patenting rejections over applications 10/227,161 and 10/161,076. Accordingly, Applicant understands that the

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provisional double patenting rejections over applications 10/227,161 and 10/161,076 are overcome.

REQUEST FOR WITHDRAWAL OF PROVISIONAL
DOUBLE PATENTING REJECTIONS OVER 09/983,234 AND 09/026,353

Claims 1-13 stand “provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims one 9-14, 16-19, 23-30, 32, 33, 37-50, 52-56, 84-132 of copending Application No. 09/863,234 in view of Restle et al. (2003/0130599). Restle et al teach a system of negative pressure that can be utilized to stimulate bone growth or to treat the tissue of soft body part. Therefore, Restle et al., it would have been obvious to one having ordinary skill in the art to modify the copending claims to include bone as taught by Restle et al in order to stimulate bone growth. The copending claims already recite the treatment of repairing soft tissue. Restle et al teach the details of the system that would provide the recited function.” Applicant draws the Examiner’s attention to the issuance of Application No. 09/863,234 as US Patent 7,216,651.

Claims 1-13 stand “provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-41, 43-46, 71-80, 83-86 of copending Application No. 09/026,353 in view of Restle et al. (5,717,030). Restle et al teach a system of negative pressure that can be utilized to stimulate bone growth or to treat the tissue of soft body part. Therefore, Restle et al., it would have been obvious to one having ordinary skill in the art to modify the copending claims to include bone as taught by Restle et al in order to stimulate bone growth. The copending claims already recite the treatment of repairing soft tissue. Restle et al teach the details of the system that would provide the recited function.” Applicant draws the Examiner’s attention to the issuance of Application No. 09/026,353 as US Patent 7,198,046.

Applicants respectfully submit that the provisional double patenting rejections over copending application numbers 09/863234 (‘234 application) and 09/026353 (‘353 application) quoted above are inappropriate in the instant case, for at least the reason that it not is obvious to modify either the ‘234 application or ‘353 application to treat bone or other hard tissue in view

of Restle. (Since a “double patenting rejection of the obviousness-type is ‘analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. 103’ ”, Applicants’ arguments against the double patenting rejecting are phrased in the analogous 103 terminology. (MPEP, p 800-21, Rev. 3, August 2005).)

The `234 and `353 applications are directed to devices and treatment methods for reduced pressure therapy of soft tissues. The applications teach that soft tissues might be amenable to treatment by reduced pressure therapy, because soft tissue can contract and deform in response to the application of reduced pressure. That is, the reasons for successful treatment were postulated to be due to mechanisms that could be expected to affect soft tissue but not hard tissue to a significant degree. Nowhere in the copending claims of the `234 and `353 applications is the term “bone tissue” is to be found. Indeed, the word “bone” is not found anywhere in the copending claims of the `234 and `353 applications.

In contrast, Applicants’ claimed invention is directed to an apparatus and method for promoting bone growth through the application of reduced pressure to the tissue to be grown. The term “reduced pressure” is defined in the instant application (as well as the `234 and `353 applications) as meaning “pressure that is below ambient atmospheric pressure.” (Application at paragraph [0006]). Thus, when each of independent claims 1, 2, 3, 4, 12, and 13 variously recite “applying a reduced pressure” and/or “maintaining the reduced pressure”, Applicant’s claims recite applying and/or maintaining a “pressure that is below ambient atmospheric pressure.” Further, Applicant discloses and variously claims that the source of “below ambient atmospheric” pressure is a “vacuum system”, “vacuum means”, or “source of suction”. Thus, Applicant’s invention relates to applying below-atmospheric pressure from a vacuum system or source to damaged bone tissue. That is, Applicant’s invention applies at least a partial vacuum to the space around the damaged bone tissue to create a region of below-atmospheric pressure at the damaged bone tissue. “Maintaining the reduced pressure” that has been applied or provided is another feature of Applicant’s claimed invention.

In contrast, Restle discloses the antithesis of applying and maintaining reduced (below-atmospheric) pressure therapy as disclosed in the `234 and `353 applications. Applicant’s claimed methods for administering a pressure that provides below-atmospheric pressure treatment to a damaged bone. Restle does not disclose or relate to a device or method for

producing a source of pressure that is below atmospheric pressure, such as a vacuum system, as disclosed by Applicant. To the contrary, Restle discloses an acoustic wave device that uses various techniques “to generate the shockwaves, for example, electrohydraulic, electromagnetic, piezoelectric, or ballistic generation.” (Restle at paragraph [0010].) These “acoustic shockwaves [are used], for example, for destroying bodily concretions, and kidney stones in particular.” (Restle at paragraph [0003].) One skilled in the art understands that the shockwaves generated by the Restle device are useful for treating kidney stones, because the shockwaves pulverize the kidney stones due in part to the great positive pressure generated by the shockwaves.

In other words, the Restle device is understood by one skilled in the art as a device that has an effect on hard bodies, such as kidney stones, due to the great pulverizing pressures that are generated by the device. At the same time, one skilled in the art also knows that reduced pressure devices that utilize a vacuum to generate reduced pressure, such as that disclosed in the '234 and '353 applications, cannot be used to treat hard bodies, such as kidney stones. Reduced (below-atmospheric) pressure cannot be used to pulverize kidney stones or have the same effect on kidney stones as the pressure shock wave device of Restle. Thus, as far as hard bodies such as kidney stones are concerned one skilled in the art of the time of Applicant's invention would know that below-atmospheric pressure and shockwaves are not interchangeable and cannot be expected to have the same effect on bodily tissues. Therefore, just as one skilled in the art at the time of Applicant's invention would know not to apply reduced pressure to a kidney stone, one skilled in the art would not find it obvious to apply reduced pressure to bone tissue based on Restle. Restle discloses that it is useful “for destroying bodily concretions, and kidney stones in particular [and that] [s]hock waves are similarly used to stimulate bone growth...”. (Restle at paragraph [0003].) However, one skilled in the art would have known that reduced pressure was not suitable for kidney stones and therefore had no reason expect that reduced pressure would be suitable for other hard bodies, such as bone tissue. There would have been no reasonable expectation of success. To the contrary, one skilled in the art at the time to Applicant's invention would have predicted a lack of success in using reduced pressure with bone tissue. That is, Restle suggests against or teaches away from using reduced pressure on bone tissue.

Moreover, the text of the '234 and '353 applications discloses physiological mechanisms

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which make reduced pressure successful, and these mechanisms cannot be predicted or expected to occur when using an acoustic pressure or shockwave device such as that disclosed by Restle. For example, the '234 and '353 applications teach that "[c]losure of an open wound requires inward migration of surrounding epithelial and subcutaneous tissue." (US 2001-0029956 A1, paragraph [0002], second sentence. Applicants cite to US 2001-0029956 which is the published '234 application, which also pertains to the '353 application, since the '353 application is a continuation of the '234 application.). "In operation, a method of treating tissue damage is provided which comprises applying a negative or reduced pressure to a wound over an area sufficient to promote the migration of epithelial-and subcutaneous tissue toward the wound and for a time period sufficient to facilitate closure of the wound." (Emphasis Added. US 2001-0029956 A1, paragraph [0012], first sentence.). Moreover, US 5,645,081, incorporated by reference in the '234 and '353 applications, teaches that "[t]he use of negative pressure provides tension on this border tissue that causes accelerated tissue migration [which] also causes within the wound increased formation of granulation tissue, a matrix of collagen, fibronectin, and hyaluronic acid carrying macrophages, fibroblasts, and neovasculature that aids in healing." (Emphasis Added. US 5,645,081, column 2, lines 51-58.).

There is no disclosure in Restle that the success of treatment with shockwaves involves in any way tissue migration or any of the other effects disclosed in the '234 and '353 applications. In addition, the term "negative pressure pulse" as used in Restle is not the same as Applicant's claimed "reduced [below-atmospheric] pressure" that is provided and maintained by a vacuum system/means. Indeed, Restle does not clearly indicate that the "negative pressure pulse" is a pressure below atmospheric. Restle states that "[a]coustic shock waves are characterized by a short positive pressure pulse exhibiting a steep rise and high amplitude followed by a negative pressure pulse of low amplitude and a longer time." (Restle at paragraph [0003]. Emphasis added.) Restle states that a positive (above atmospheric) pressure pulse of high amplitude is followed by a negative pressure pulse of low amplitude. Thus, since the pressure is first increased by a high amplitude pulse and then subsequently decreased presumably from that point by a low amplitude negative pressure pulse, the resulting pressure after application of the negative pressure pulse may ostensibly be positive (above-atmospheric) and not a "reduced (below-atmospheric) pressure" as claimed by Applicant. Moreover, it is not

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obvious to combine a device for applying and maintaining a reduced pressure as disclosed in the '234 and '353 application with the device of Restle that not only generates a positive pressure pulse, but a positive pressure pulse exhibiting a "high amplitude." Using the device of Restle to produce a positive pressure pulse of high amplitude is directly opposite to Applicant's claimed invention of providing and maintaining a reduced (below-atmospheric) pressure, as variously recited in independent claims 1, 2, 3, 4, 12, and 13.

Consequently, for at least all the above reasons, it is not even "obvious to try" using reduced pressure instead of shockwaves to treat bone tissue. The use of reduced (below-atmospheric) pressure to treat bone is neither predictable nor expected to succeed based on the proposed combination of Restle and the '234 and '353 applications. Moreover, there is certainly no teaching, suggestion, or motivation to modify '234 and '353 applications in view of Restle to arrive at Applicant's claimed invention.

To summarize the above arguments in terms of the seven "rationales" recently set forth by the US PTO "Examination guidelines for determining obviousness under 35 USC 103 in view of the Supreme Court decision in KSR...", the use of reduced pressure to treat bone tissue based on Restle and '234 and '353 applications does not lead to a predictable result or a reasonable expectation of success, for at least the reasons set forth above. In addition, substituting reduced (below-atmospheric) pressure for shockwave that includes a "positive pressure pulse exhibiting a steep rise and high amplitude" is not "obvious to try" or the "use of known technique to improve similar devices (methods, or products) in the same way". And, certainly the above arguments make clear that there is no teaching, suggestion, or motivation to modify '234 and '353 applications in view of Restle to arrive at Applicant's claimed invention.

Hence, for all the above reasons, Applicant respectfully requests that the examiner withdraw the provisional double patenting rejections of claims 1-13 in view of Restle.

REJECTIONS UNDER 35 U.S.C. 102

Claims 4 and 13 stand rejected under 35 U.S.C. 102 as being anticipated by Restle. Claims 4 and 13 as amended above recite the feature of "providing a porous material at the site of the bone defect", which feature Restle fails to disclose. Consequently, released this reason Restle fails to disclose each and every element recited in claims 4 and 13. Moreover, being an

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acoustic device that produces sound waves and shock waves there would be no purpose in modifying Restle to include a porous material for at least the reasons cited above with regard to the double patenting rejections. Thus, it would also not be obvious to add a porous material to Restle to arrive at Applicant's claimed invention, and claims 4 and 13 are not obvious in view of Restle.

REJECTIONS UNDER 35 U.S.C. 103(a)

Claims 1-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over "Argenta et al. (5,636,643) in view of Restle et al. (2003/0130599)." Argenta 5,636,643 is a parent application to the '234 and '353 applications, and consequently, the arguments presented above requesting withdrawal of the provisional double patenting rejection of the '234 and '353 applications in view of Restle also apply to the instant rejections under 35 U.S.C. 103. Accordingly, for at least the reasons presented above Applicants respectfully submit that claims 1-13 are patentable over Argenta 5,636,643 in view of Restle. Hence, Applicant respectfully requests that the rejection of claims 1-13 be withdrawn.

Respectfully submitted,

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